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10/614,408	07/02/2003	Michele Boix	17571 (AP)	4873

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EXAMINER

SILVERMAN, ERIC E

ART UNIT	PAPER NUMBER
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1618

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

The response filed 1/8/2009 was received. Claims 22-26, 70-78, 88, 90-93, and 95-101 are pending; claims 22-26 and 95-101 are withdrawn; claims 70-78, 88, and 90-93 are treated on the merits in this action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 70-78, 88, and 90-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montanari in view of US 6,365,632 to Perricone and US 5,534,261 to Rogers.

Montanari teaches gamma irradiated PLGA microparticles with the drug CLO. The particle diameters are within the range of instant claims. Although the particles are not prepared by irradiation at 5 C or less, they are prepared by irradiation under vacuum. In such cases, the aggregation decreases as compared to the particles before irradiation, or as compared to the particles when irradiated in air. The aggregation changes are reflected by the decrease in particles sizes in Figure 2B for CLO irradiated under vacuum. The particles are also lyophilized. Thus, although they are prepared by a different method, the microparticles of Montanari are identical to those produced by instant product by process claims except that instant claims use a different drug (tazarotene) than Montanri.

Perricone teaches that tazarotene is a useful retinoid active agent for treating conditions treatable with retinoids. Rodgers shows that retinoids can be used with gamma irradiated microparticles.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use tazarotene in the particles of Montanari. The motivation to do so is to obtain the art-recognized therapeutic benefits of this agent. Because Rodgers teaches that retinoids can be formulated in irradiated PLGA microparticles, the artisan would enjoy a reasonable expectation of success.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive. Applicants argue that none of the cited references indicate that irradiation of PLA or PLGA particles with tazarotene at temperatures less than 5 C yields particles that have reduced aggregation when compared to the same particles aggregated at room temperature. This statement is correct, but it has no bearing on the obviousness rejection.

The claims at issue are product-by-process claims. In such claims, the process is only given patentable weight insofar as it conveys a patentable distinction on the product. Here, the claimed product is obvious, although the art suggests a different method of making it. The method of the art does not recognize that the method of the claims would also make de-aggregated particles; nonetheless the art suggests the same de-aggregated particles as those claimed can be made by irradiation under vacuum.

Applicant also argues that the effect of gamma irradiation on aggregation of drug loaded particles is unpredictable. This is understood to be an argument that the artisan would not expect to succeed in achieving the claimed particles, even if they are suggested by the art. In response, the evidence of record clearly indicates that the effect of gamma irradiation on drug loaded particles is, in the whole, unpredictable. However, Montanari teaches the conditions for achieving de-aggregated particles after irradiation. Montanari teaches that this can be achieved by irradiation under vacuum. The appropriate question here is not whether irradiation on the whole leads to unpredictable results, but whether or not irradiation under vacuum gives predictable results. If it is unpredictable, applicants' argument is persuasive; if not, the obviousness rejection is still proper.

In analyzing the predictability of irradiation of PLGA under vacuum, the applicable evidence of record is Montanari. No other reference teaches vacuum irradiation. Figure 2 of Montanari is an excellent summary of the applicable results. In this figure, both placebo particles and drug loaded particles are irradiated under vacuum and in air. This experiment is performed on particles with a variety of sizes before irradiation; tests were performed on three different (original) size placebo particles, and four different (original) size drug particles. The sizes of particles after irradiation in air and under vacuum are compared to the particle size before irradiation.

The results are telling. While there are a few outlying data points, on the main the particles are less aggregated when irradiated under vacuum then when irradiated in air.

Art Unit: 1618

Obviousness need not involve complete predictability; a reasonable expectation of success is sufficient. The art's method of irradiation under vacuum is generally predictable, and provides the artisan with a reasonable expectation of success. Thus the showing in Montanari is sufficient to support a holding of obviousness over the combination of references cited.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Examiner, Art Unit 1618